

certain value, then it is determined that the transfer of molecules is abnormal, and the application of output voltage is interrupted. However, in this method, a load of a human body at the initial stage of energization may be as high as several M Ω to several tens M Ω at low output voltages and it is difficult to determine whether there is conduction or non-conduction of current. Therefore, a relatively high voltage is applied initially to determine whether there is conduction or non-conduction.

International Publication No. WO96/17651 discloses an apparatus in which the transdermal is first hydrated for a certain length of time before electrically energizing a human body, then the output current is measured and the output voltage is interrupted if the measured output current is out of a certain range. International Publication No. WO88/08729 discloses another related technique, i.e., an apparatus in which when an over-current flows, the supply of output current is terminated.

With these apparatus, there are problems about the DC impedance used as a measure means of conduction such that differences in individual are large and that the impedance is high and even higher at lower output voltages and that the impedance is highly sensitive to the hydration conditions. Therefore, conventionally, conduction in iontophoresis cannot be determined with a sufficient level of accuracy.

In order to overcome the aforementioned problems, although it is considered in such a way that a relatively high

voltage at the initial stage of energization may be applied or sufficient hydration of the transdermal may be employed to increase detection sensitivity of impedance, it produces new problems that users may feel uncomfortable or that the states of current conduction cannot be measured until the hydration is sufficient.

An object of the present invention is to overcome the aforementioned problems and to provide a device for iontophoresis that can determine conduction states with a high level of accuracy.

DISCLOSURE OF THE INVENTION

The inventors have concentrated in order to achieve the aforementioned object. The inventors focussed on the capacitance that exists in the transdermal or the transmcosal, and they found that detecting the current (reactive current) that flows through the capacitance or the charges (residual voltage) stored in the capacitance allows determining of the conduction states, and then made the present invention accordingly. The present invention allows determining of not only conduction states due to complete detachment of a part for applying iontophoresis to the transdermal or poor contact at a terminal or cracks in the electrode, but also the conditions of the transdermal to which iontophoresis is applied.

A device for iontophoresis according to the present invention comprises first means for detecting a capacitance stored in transdermal or transmcosal and second means for

determining a conduction state of current into the transdermal or the transmcosal based on the output detected by the first means. The first means can be, for example, a detection circuit for a reactive current flowing through the transdermal or the transmcosal or a detection circuit for a residual voltage developed in the transdermal or the transmcosal. If the detection circuit of the reactive current is used, the voltage applied to the subject has a waveform such as an AC wave, a rectangular wave, or a DC wave on which a rectangular wave is superimposed, or a DC wave on which an AC wave is superimposed. If the detection circuit of residual voltage is used, the voltage applied is an intermittent waveform.

With a method for determining the operation of an iontophoresis apparatus according to the present invention, a capacitance in the transdermal or the transmcosal is detected to determine the operation of a conduction state of current through the transdermal or the transmcosal. The capacitance is detected by detecting a reactive current that flows through the transdermal or the transmcosal, or detecting a residual voltage developed in the transdermal or the transmcosal.

An iontophoresis apparatus according to the present invention comprises a preparation for iontophoresis, holding a drug, and a device for iontophoresis having means for generating an electrical output to supply a drug from the preparation into the transdermal or the transmcosal and means for detecting a value indicative of a capacitance of the